

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Boyce et al.

EXAMINER: Prebilic, P.

SERIAL NO.: 09/543,268

GROUP ART UNIT: 3738

FILED: April 5, 2000

DOCKET: 285-79 CON

FOR: OSTEOIMPLANT AND
METHOD FOR
ITS MANUFACTURE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF TODD M. BOYCE
AND ALBERT MANRIQUE UNDER 37 C.F.R. § 1.131

Sir:

We, Todd M. Boyce, Ph.D., and Albert Manrique, declare and say as follows:

1. Todd M. Boyce is a Senior Scientist in the employ of Osteotech, Inc., the assignee of record of the subject patent application, and a named inventor therein.
2. Albert Manrique was, during the period of all of the acts hereinafter described, a Senior Research Scientist in the employ of Osteotech, Inc., and a named inventor in the subject patent application.
3. In the Office Action mailed April 2, 2003, the Examiner has maintained the rejection of Claims 1-7, 9-21, 23-43, 45-61, 63-80 and 82-134 of the subject patent application under 35 U.S.C. § 102(e) as unpatentable over Boyce et al. U.S. Patent No. 5,899,939 ("Boyce et al. '939") which issued on May 4, 1999 on original application Serial No. 09/009,997 filed January 21, 1998.

4. Applicants filed a Response to the Office Action on May 16, 2003 accompanied by the Combined Declaration of Todd M. Boyce and Albert Manrique under 37 C.F.R. § 1.131. In the Advisory Action mailed May 28, 2003, the Examiner stated that “[t]he declaration was not sufficient to show that the applicant had completed the invention, that it worked for its intended purpose, and that it had the claimed properties such as compression strength.”

5. The subject application was filed on April 5, 2000 as a continuation of U.S. patent application Serial No. 09/020,205 filed February 6, 1998, which issued as U.S. Patent No. 6,123,731 on September 26, 2000. The subject application is entitled to an effective filing date of February 6, 1998.

6. We make this declaration under 37 C.F.R. § 1.131 in order to present a showing of facts evidencing the making of the claimed invention in this country prior to the January 21, 1998 filing date of the application underlying the grant of the Boyce et al. '939 patent. Specifically, we make this declaration in order to present a showing of facts which, in character and weight, establish the conception of the invention of Claim 1 and that of the other rejected claims prior to the January 21, 1998 filing date of the aforesaid Boyce et al. application coupled with due diligence from prior to said date to the February 6, 1998 effective filing date of the subject application.

7. All of the acts hereinafter described took place in the United States.

8. Attached hereto is Exhibit A, a copy of (1) a facsimile draft patent application received from outside patent counsel, each page of which bears the date of January 9, 1998, as marked up by Dr. Boyce, (2) outside patent counsel's facsimile cover

sheet dated January 9, 1998 for the draft patent application as sent to Dr. Boyce and (3) an internal memorandum from Dr. Boyce dated January 9, 1998 attaching documents (1) and (2) for distribution to the individuals listed in the memorandum ("distribution list") and requesting their review and comments by January 19, 1998. The draft patent application as marked up by Dr. Boyce evidences the conception of the invention of amended Claim 1 herein prior to the January 21, 1998 filing date of the application underlying the grant of the Boyce et al. '939 patent as shown by the following side-by-side comparison of the elements of Claim 1 of the subject application and corresponding disclosure in the marked-up draft patent application constituting part of Exhibit A:

Claim 1 of the Subject Application	Marked-up Draft Patent Application
<p>1. An osteoimplant which comprises a solid aggregate of bone-derived elements selected from the group consisting of superficially demineralized bone-derived elements, substantially completely demineralized bone-derived elements and mixtures thereof, adjacent bone-derived elements being bonded to each other through chemical linkages between their surface-exposed collagen, provided, that where substantially all of the bone-derived elements are substantially completely demineralized bone-derived elements the osteoimplant contains at least one additional component selected from the group consisting of reinforcing particles and fillers, and wherein the solid aggregate of bone-derived elements possesses a compression strength of from about 10 to about 200 MPa.</p>	<p>Page 5, lines 1-7 discloses:</p> <p>In keeping with these and other objects of the invention, there is provided an osteoimplant which comprises a solid aggregate of bone-derived elements initially presenting surface-exposed collagen, with adjacent bone-derived elements being bonded to each other through chemical linkages between their surface-exposed collagen.</p> <p>Page 6, lines 15-21 discloses:</p> <p>The expression "surface-exposed collagen" shall be understood to refer to the result obtained by demineralizing the aforementioned bone-derived elements, the demineralization ranging from substantially complete (in which case the bone-derived elements are primarily collagen) to superficial (in which case only the surfaces of the bone-derived elements present exposed collagen).</p>

Claim 1 of the Subject Application	Marked-up Draft Patent Application
	<p>Page 9, lines 15-18 discloses:</p> <p>In addition to containing bone-derived elements, the osteoimplant of this invention can optionally possess one or more other components such as reinforcing particles, fibers, fillers, bone-growth inducing substances...</p> <p>Page 9, lines 7-14 discloses:</p> <p>Accordingly, when an osteoimplant exhibiting relatively high compression strength is desired, e.g., on the order of from about 20 to about 200 MPa, and preferably from about 40 to about 150 MPa, it is necessary to employ bone-derived elements which retain a high proportion of their original mineral content or, stated another way, which have only been superficially demineralized.</p>

A similar side-by-side comparison will show that the subject matter of the other claims presented herein is described by the marked-up draft application constituting part of Exhibit A.

9. From January 9, 1998, the date Dr. Boyce distributed Exhibit A to those on the distribution list referred to in paragraph 8, to on or about January 28, 1998, the marked-up draft was undergoing review by individuals on the distribution list. On January 28, 1998, Dr. Boyce sent a facsimile memorandum to outside counsel with a list

of proposed changes to be made to the draft application. Attached hereto as Exhibit B is a copy of this memorandum and its cover sheet.

10. Between January 28, 1998 and February 5, 1998, outside counsel revised the draft application based at least in part on the contents of Exhibit B and forwarded the revised application, with formal documents, to applicants for their review and prospective execution. On February 5, 1998, as evidenced by Exhibit C (cover letter referencing the executed application), applicants executed the application returning same to outside counsel with instructions to file in the PTO.

11. The application was filed on February 6, 1998 as Serial No. 09/020,205. This application, of which the subject application is a continuation, is a constructive reduction to practice of the invention disclosed in the marked-up draft application constituting part of Exhibit A.

12. The facts presented in paragraphs 8 to 11 and the referenced documentary exhibits establish conception of the invention of the claims herein prior to the January 21, 1998 filing date of the Boyce et al. '939 patent coupled with due diligence from prior to said date to the filing of application Serial No. 09/020,205 on February 6, 1998.

13. We each further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

§ 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: _____, 2003

Todd M. Boyce

Dated: 9/30, 2003

Albert Manrique

JCT:mg